

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12 613



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12613

A. Patient information

1 Patient identifier 	2 Age at time of event: 45 or Date of birth:	3 Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4 Weight 150 lbs or kgs
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B. Adverse event or product problem

<input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)	
Outcomes attributed to adverse event (check all that apply)	
<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input checked="" type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input type="checkbox"/> other:	
5 Date of event (mo/day/yr) 10/22/97	6 Date of this report (mo/day/yr) 10/27/97

Describe event or problem

Hypertensive Emergency with
BP 240/130 !!! No previous
history of HTN. No current
meds other than those listed
as suspect meds.

See
enclosed
copies of
labels

C. Relevant tests/laboratory data, including dates

NA

D. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)

NA

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)		3 Therapy dates (if unknown, give duration) from/to (or best estimate)	
#1 Thermobiotics Supplement		#1	
#2 Hypolytics / Metabolics		#2	
2 Dose, frequency & route used		5 Event abated after use stopped or dose reduced	
#1 1/2 Q12 Hrs		#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 1/2 Q12 Hrs		#2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
4 Diagnosis for use (indication)		8 Event reappeared after reintroduction	
#1 "Weight loss" "energy"		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 "Vitamin Supplement"		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6 Lot # (if known)		7 Exp. date (if known)	
#1 705172C		#1	
#2		#2	
9 NDC # (for product problems only)			
10 Concomitant medical products and therapy dates (exclude treatment of event)			
None			

D. Suspect medical device

1 Brand name		4 Operator of device	
2 Type of device		<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other	
3 Manufacturer name & address		5 Expiration date (mo/day/yr)	
6 model #		7 If implanted, give date (mo/day/yr)	
catalog #		8 If explanted, give date (mo/day/yr)	
serial #			
lot #			
other #			
9 Device available for evaluation? (Do not send to FDA)			
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on (mo/day/yr)			
10 Concomitant medical products and therapy dates (exclude treatment of event)			
000001			

E. Reporter (see confidentiality section on back)

1 Name & address		phone #	
2 Health professional?		3 Occupation	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		Physician	
4 Also reported to			
<input type="checkbox"/> manufacturer		<input checked="" type="checkbox"/> distributor	
<input type="checkbox"/> user facility			
5 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input type="checkbox"/>			



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178